



2. Defendants CSL Limited, CSL Behring LLC, and Baxter International Inc. develop, manufacture, and sell Plasma-Derivative Protein Therapies (defined below), which are used primarily by hospitals and other healthcare providers to treat critically ill patients suffering from, among other diseases, various immune disorders. Defendant Plasma Protein Therapeutics Association (“PPTA”) is the trade association for plasma-protein therapy manufacturers. CSL and Baxter are important members of, and occupy significant leadership positions within, the PPTA.

3. While the conspiracy began in mid-2003, Defendants laid the groundwork for it in the late 1990s, when safety-related plant closures led to supply shortages in the industry that triggered government intervention. In June 1999, the vice-president of the plasma manufacturing industry’s trade association (a precursor to the PPTA), several consulting firms, and government representatives met to explore ways to increase industry inventory and supply transparency so that future shortages could be averted. Defendants also used this meeting as an opportunity to begin exploring ways to increase the level of transparency among themselves. Over the next few years, Defendants developed a data monitoring system that would enable them to know each supplier’s current distribution and inventory levels. The industry used the pretext of avoiding future supply shortages to justify the information exchange, when in fact the industry had every intention of driving down supply. Indeed, CSL’s Chief Economist presciently noted that “economics can help [us] understand how to loosen the shackles of competition.” He proved to be right, as this system would serve as an excellent mechanism to effectuate and monitor Defendants’ anticompetitive conspiracy.

4. Meanwhile, the government intervention served its purpose. Plasma manufacturers implemented stricter safety guidelines and, once the temporarily closed plants came back on line, increased production of Plasma-Derivative Protein Therapies. The early 2000s witnessed a period of abundant supply of Plasma-Derivative Protein Therapies, and manufacturers, including Baxter and CSL, suffered severe drops in profitability.

5. These sinking profits spurred Baxter and CSL to unlawfully agree to reduce supply and fix prices of Plasma-Derivative Protein Therapies. As more fully described below, Baxter and CSL took various actions, the bulk of which formed the crux of the conspiracy, to reduce supply and increase profitability. *First*, Baxter and CSL gained significant market share by acquiring competitors and soon thereafter closed many of these newly acquired plants, thereby reducing industry supply. *Second*, they worked with the PPTA to refine the data monitoring system, initiated in 1999, so that they could determine their fellow suppliers' current inventory and supply levels. *Third*, they signaled to each other and to fellow suppliers the desirability of restricting supply to the marketplace. *Fourth*, they frequently engaged in anticompetitive discussions involving supply and pricing issues at PPTA meetings, and upon information and belief, continued those discussions privately at bars and restaurants after trade association meetings and at business meetings. *Fifth*, in an effort to ward off government intervention once the conspiracy began to produce results, Baxter and CSL, in coordination with the PPTA, publicly and falsely denied supply shortages, significantly over-reported industry supply figures, and misleadingly blamed Medicare reimbursement rates for patients' difficulties in obtaining these crucial therapies.

6. Beginning in the early 2000s, and particularly between 2003 and 2005, Baxter and CSL made key competitor acquisitions so that they would be in a better position to control the supply of Plasma-Derivative Protein Therapies. Shortly after many of these acquisitions, Baxter and CSL curbed output at many of the newly acquired facilities. By the latter part of this period, only five suppliers of these therapies remained, and Baxter and CSL each had substantial shares of the market for each therapy.

7. In late 2002, the PPTA, with the extensive involvement of Baxter and CSL, launched a new data monitoring system. The system, developed in close collaboration with economists and data collection experts, identified benchmark ratios for inventory versus distribution levels of Plasma-Derivative Protein Therapies. As the industry consolidated, fewer and fewer members reported data, until there were only five suppliers left, and Baxter and CSL each represented more than 25% of the industry supply. Given that there only five suppliers, that two of them each possessed over 25% of the market for each therapy, and that the inventory and distribution levels being shared were current in nature, Defendants were able to use this system to determine each supplier's present inventory and supply levels, and thus use it to effectively monitor and police the conspiracy.

8. The PPTA asserted that its data gathering effort promoted the public good by helping to alert both manufacturers and the government to potential impending supply shortages, but this was mere pretext. The PPTA's efforts to gather and monitor supply data facilitated anticompetitive information exchange among manufacturers and ultimately assisted Defendants in concealing their conspiracy by providing a ready mechanism with which to report inflated supply numbers.

9. In late 2003, the anticompetitive communications among Defendants began in earnest. The PPTA, as well as Baxter and CSL, signaled the industry to restrict the supply of Plasma-Derivative Protein Therapies. Jan Bult, President of the PPTA, publically stated that “we will see—and this is my prediction—that individual companies, in response to their economic challenges, will tighten supply.” CSL and Baxter similarly signaled each other and the industry, through analysts, investor calls, and the press, to restrict the supply of Plasma-Derivative Protein Therapies.

10. Executives from Baxter and CSL also regularly met privately in bars or restaurants after trade association and other industry meetings. Upon information and belief, Baxter and CSL routinely discussed supply and pricing of Plasma-Derivative Protein Therapies during these private meetings.

11. Nor were the anticompetitive discussions restricted to the private confines of bars or restaurants. For example, the minutes from ostensibly legitimate meetings among Baxter and CSL were regularly “scrubbed” of anticompetitive discussions that occurred during the meetings. Additionally, executives from smaller suppliers of Plasma-Derivative Protein Therapies have voiced concerns that CSL and Baxter had exchanged what they believed was anticompetitive information relating to the supply and pricing of Plasma-Derivative Protein Therapies.

12. Once the conspiracy was underway, Defendants took active steps to conceal their illicit activities. In 2006, patients and doctors jointly asked the government to declare the shortage of Plasma-Derivative Protein Therapies a public health emergency. Defendants, leery of increased government involvement similar to that which occurred in the late 1990s, employed two primary strategies to stop this from

happening. Defendants, via the PPTA, denied supply shortages and significantly over-reported the supply of the therapies in the marketplace. Defendants, again via the PPTA, also sought to shift the focus away from reports of a supply shortage by focusing on Medicare reimbursement rates as the purported sole cause for patients' access problems. By denying shortages and manipulating the debate, Defendants managed to avoid a government declaration of a public health emergency and maintained and concealed their conspiracy.

13. One thing threatened the continuing vitality of Defendants' conspiracy: a non-collusive plasma manufacturer with the capacity to significantly increase industry output. Talecris Biotherapeutics Holdings Corporation ("Talecris") was the only company with the manufacturing capacity capable of undermining CSL and Baxter's plans. In early 2009, with the public support of ostensible competitor Baxter, CSL attempted to acquire Talecris and thus neutralize the only significant threat to the conspiracy.

14. Soon thereafter, the Federal Trade Commission ("FTC") filed an administrative complaint that sought to block CSL Limited's attempted acquisition of Talecris on the basis that the deal would substantially reduce competition in the United States for Plasma-Derivative Protein Therapies. Soon after the FTC filed its complaint, CSL chose to abandon the proposed acquisition. Significantly, the FTC's complaint, accompanying press release, and subsequent filings support many of Plaintiff's allegations.

15. In an FTC press release accompanying the filing of the lawsuit, the Director of the FTC's Bureau of Competition stated that "[s]ubstantial consolidation has

already occurred in the plasma protein industry, and these highly concentrated markets are already exhibiting troubling signs of coordinated behavior.” Moreover, the FTC alleged that if the proposed acquisition were approved, Defendants “would face no remaining significant obstacle in their efforts to coordinate and tighten supply conditions for the relevant products.”

16. In evaluating the anticompetitive effects that the deal would produce, the FTC discovered evidence from Defendants’ own files that “suggests a strong possibility of ongoing coordinated interaction between firms in the plasma industry.” The FTC has remarked that some of the language discovered in Defendants’ documents “is similar to language that in other instances has been found to be evidence supporting an illegal price fixing conspiracy,” and thus could expose Defendants to “possible treble damages actions.”

17. The FTC’s complaint describes, among other things, “troubling signs of coordinated behavior” that Defendants have undertaken, including signaling—*i.e.*, the intentional sharing of competitive information for purposes of seeking to ensure that manufacturers all are restraining output and curbing growth, thereby promoting higher prices.

18. The FTC also notes that Defendants have used specific key words to: (1) suggest to each other that increasing the production of Plasma-Derivative Protein Therapies could hurt the firms’ collective ability to reap the significant profits that they all gained during an extended period where demand exceeded supply for these products; (2) remind each other of how, during a period when supply increased, prices and profitability for firms dropped substantially; and (3) encourage one another to increase

supply only incrementally to keep pace with demand, and not increase supply to the extent the firms actually would have to compete with one another for market share.

19. As a result of Defendants' conspiracy, many patients were forced to go without critical Plasma-Derivative Protein Therapies. According to an IDF survey of physicians conducted in 2005, 33% of doctors had significant difficulty obtaining Ig, one of the therapies at issue. These doctors also reported that 40% of those patients denied access to their Ig therapy had suffered adverse health effects.

20. Defendants' coordinated efforts to restrict supply have produced favorable financial results for Defendants, however, as the prices of Plasma-Derivative Protein Therapies have risen dramatically since 2003, and Defendants have enjoyed large profit margins ever since.

21. As a result of the conspiracy, prices for Plasma-Derivative Protein Therapies were higher than they otherwise would have been. Beginning on July 1, 2003, and continuing through the present, prices for Plasma-Derivative Protein Therapies have increased substantially. Plaintiff and all others similarly situated paid supra-competitive prices for these products, and have suffered injury to their business and property. Seeking recovery for the financial harm that the conspiracy has inflicted, Plaintiff brings this action on behalf of itself and all those similarly situated that purchased Plasma-Derivative Protein Therapies in the United States directly from Defendants from July 1, 2003 through the present.

#### **JURISDICTION AND VENUE**

22. Plaintiff brings this action under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages and costs of suit, including reasonable



attorneys' fees, against Defendants for the injuries that Plaintiff and the other Class members have suffered from Defendants' violations of Section 1 of the Sherman Act, 15 U.S.C. § 1.

23. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337 and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26.

24. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a) and 22 and 28 U.S.C. § 1391(b), (c) and (d) because during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the affected interstate trade and commerce discussed below has been carried out in this District.

25. This Court has personal jurisdiction over each Defendant because each Defendant: transacted business throughout the United States, including in this District; sold Plasma-Derivative Protein Therapies throughout the United States, including in this District; had substantial contacts with the United States, including in this District; or engaged in an illegal scheme and price-fixing conspiracy that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

## **PARTIES**

### **PLAINTIFF**

26. Plaintiff University of Utah, a body politic and corporate of the State of Utah, is acting on behalf of its University of Utah Hospitals & Clinics ("UUHC"). The University of Utah and UUHC have their principal place of business in Salt Lake City, Salt Lake County, Utah.. Plaintiff, through its UUHC, operates approximately 469 beds.

During the Class Period, Plaintiff purchased Plasma-Derivative Protein Therapies directly from one or more Defendants. As a result of the conspiracy alleged, Plaintiff was injured in its business or property.

### **DEFENDANTS**

27. Defendant CSL Limited is a company incorporated and domiciled in Australia, with its principal place of business located at 45 Poplar Road, Parkville, Victoria, 3052, Australia. CLS Limited is the second-largest supplier of Plasma-Derivative Protein Therapies in the world. It produces and sells biotherapies indicated for the treatment of several rare primary immune deficiency diseases, coagulation disorders, and inherited respiratory disease. CSL Limited is a vertically integrated company. It owns and operates one of the world's largest plasma collection networks, CSL Plasma, with collection facilities and laboratories in Boca Raton, Florida and Marburg, Germany. It also owns and operates manufacturing sites through its wholly owned subsidiaries in Marburg, Germany and Bern, Switzerland. CSL Limited's worldwide sales for its 2008 fiscal year were about \$2.5 billion. Ig sales accounted for 34% of CSL's total sales and albumin accounted for 10% of total sales.

28. Defendant CSL Behring LLC is a wholly owned U.S. subsidiary of CSL Limited and is headquartered at 1020 First Avenue, King of Prussia, Pennsylvania 19406-0901. CSL Behring is the second largest producer of plasma products in the United States. CSL Behring's products are indicated for the treatment of coagulation disorders including hemophilia and von Willebrand disease, primary immune deficiencies, and inherited respiratory diseases. Its products also are used in cardiac surgery, organ transplantation, and burn treatment, and for the prevention of hemolytic diseases in

newborns. CSL Behring has a manufacturing site in Kankakee, Illinois. CSL Behring's sales revenue was approximately \$1.8 billion for its 2008 fiscal year.

29. Defendant Baxter International Inc. is a global, diversified healthcare company incorporated in Delaware and has its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015. Baxter is the largest producer of Plasma-Derivative Protein Therapies in the world, and is the largest producer of plasma products in the United States. Baxter is divided into three business segments: BioScience; Medication Delivery; and Renal. The BioScience business manufactures and sells, among other products, recombinant and plasma-based proteins to treat hemophilia and other bleeding disorders, and plasma-based therapies to treat immune deficiencies, alpha 1-antitrypsin deficiency, burns and shock, and other chronic and acute blood-related conditions. Baxter maintains 15 manufacturing facilities in the United States and its territories, as well as facilities in 23 other countries. Its BioScience segment has 11 manufacturing sites domestically and abroad, including sites in Hayward, Thousand Oaks, and Los Angeles, California and in Beltsville, Maryland. In 2008, Baxter's revenues exceeded \$12.3 billion, and it derives about 20% of its sales from plasma products.

30. Defendant Plasma Protein Therapeutics Association (PPTA) is an international trade association comprised of the collectors of source plasma and manufacturers of Plasma-Derivative Protein Therapies. The PPTA is headquartered at 147 Old Solomons Island Road, Suite 100, Annapolis, Maryland 21401. The PPTA consists of global and regional boards of directors which represent the geographic interests of its members. It does not include purchasers or patients of Plasma-Derivative Protein Therapies or any entities or groups that advocate for those groups' interests. The

PTTA participated in and facilitated the conspiracy during the Class Period (defined below).

### **CO-CONSPIRATORS**

31. Various other individuals, firms and corporations, not named as Defendants herein, may have participated as co-conspirators with Defendants and performed acts and made statements in furtherance of the conspiracy. Plaintiff reserves the right to name subsequently some or all of these persons as defendants.

32. Whenever in this Complaint reference is made to any act, deed or transaction of any corporation, the allegation means that the corporation engaged in the act, deed or transaction by or through its officers, directors, agents, employees or representatives while they were actively engaged in the management, direction, control or transaction of the corporation's business or affairs.

### **INTERSTATE TRADE AND COMMERCE**

33. The activities of Defendants and their co-conspirators, as described in this Complaint, were within the flow of and substantially affected interstate commerce.

34. During the Class Period, Defendants and their co-conspirators sold substantial quantities of Plasma-Derivative Protein Therapies in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

35. The conspiracy in which the Defendants and their co-conspirators participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

## **FACTUAL ALLEGATIONS**

### **THE PLASMA-DERIVATIVE PROTEIN THERAPIES INDUSTRY**

#### **Background**

36. The manufacturing process for Plasma-Derivative Protein Therapies involves: (1) plasma collection; (2) plasma testing; (3) fractionation (*i.e.*, precipitation of solids by manipulation of solution pH, temperature, etc.); (4) finishing or purification; (5) quality control; and (6) lot release. The time required to complete the full manufacturing process ranges from approximately seven months to one year.

37. The manufacturing process is highly regulated because plasma products run the risk of containing and transmitting infections. Relevant regulatory bodies include the United States Food and Drug Administration (“FDA”), state regulatory agencies, and the PPTA, which purports to operate as an industry self-regulatory body.

38. Plasma-Derivative Protein Therapies are essential for treating a number of serious illnesses, including immune deficiency diseases, coagulation disorders, and respiratory diseases. The annual cost for such treatments can exceed \$90,000 per patient in some cases.

39. Purchasers of Plasma-Derivative Protein Therapies—usually hospitals through contracts negotiated by Group Purchasing Organizations (GPOs)—will pay very high prices if necessary to make treatment available to critically ill patients. Consequently, small changes in production levels cause dramatic swings in prices for products, and producers stand to increase profits greatly by controlling output relative to demand.

40. The most prominent plasma-derivative protein therapies are: (1) Ig; (2) albumin; (3) alpha-1; and (4) Rho-D. The relevant plasma-derivative protein therapy products for purposes of this Complaint are Ig and albumin (“Plasma-Derivative Protein Therapies”).

### **Relevant Products**

#### **Ig**

41. Ig—short for immune globulin—is a widely used drug that can be administered intravenously (“IVIG” or “IGIV”) or subcutaneously (“SCIG”). IVIG, the more predominant form, has over 20 FDA-approved indications, and as many as 150 off-label uses. Ig products are antibody-rich plasma therapies that long have been used in the treatment of primary immune deficiencies (to provide antibodies a patient is unable to make) and certain autoimmune disorders where it is believed to act as an immune modulator. In addition, physicians frequently prescribe Ig for a wide variety of diseases, although these uses are not described in the product’s labeling and differ from those tested in clinical studies and approved by the FDA or other regulatory agencies in other countries. These unapproved, or “off-label,” uses constitute the preferred standard of care or treatment of last resort for many patients in varied circumstances.

42. Ig represents the largest Plasma-Derivative Protein Therapy by value. It is estimated that 70% of IVIG sold in the United States in 2007 was purchased by hospitals through contracts negotiated by GPO’s. Physician offices represented about 13% of IGIV volume, and homecare companies and specialty pharmacies represented about 17% of IGIV volume.

43. Ig is a commodity-like product for which there are no good or reasonably interchangeable substitutes.

#### **Albumin**

44. Albumin is the most abundant protein in human plasma. It is synthesized by the liver and performs multiple functions, including the transport of many small molecules in the blood and the binding of toxins and heavy metals, which prevents damage that they otherwise might cause. Albumin is used to expand blood volume and to prime heart valves during surgery.

45. Albumin generally is used in surgical and trauma settings and typically is sold to hospital groups.

46. Albumin is a commodity-like product for which there are no good or reasonably interchangeable substitutes. Physicians and hospitals regard albumin as far superior from a clinical standpoint to any potential alternatives, such as hetastarch and saline products.

#### **Relevant Geography**

47. Like pharmaceutical products, each Plasma-Derivative Protein Therapy must be approved for sale in the United States by the FDA. To obtain approval, the products must be produced from plasma collected in the United States at collection centers approved by the FDA. The products also must be manufactured at plants approved by the FDA.

48. Performing the requisite clinical trials and undergoing the FDA approval process for plasma and Plasma-Derivative Protein Therapies takes well over two years. Accordingly, Plasma-Derivative Protein Therapies sold outside of the United States are not

viable competitive alternatives for United States customers, who cannot buy products produced abroad even in the event of a price increase for products available in the United States.

## **PRE-CLASS PERIOD INDUSTRY DYNAMICS AND CONDUCT**

### **Late 1990s: Decreased Supply, Growing Demand, And Government Intervention**

49. In the late 1990s, a series of events brought about by temporary plant closures resulted in extensive changes in supply for both the domestic and global plasma-derivative protein therapy industries.

50. In 1997, in the wake of a recall of albumin produced by a company called Centeon, the FDA mandated the temporary closure of the plant then owned by Centeon at Kankakee, Illinois (which CSL Limited now owns). In 1999, the Alpha Therapeutic Corporation plant in Los Angeles, California (which Baxter now owns) temporarily closed. The shortages that resulted from these disruptions, particularly with respect to Ig, caused higher prices in the United States, spurring producers to increase plasma collections as well as output of Plasma-Derivative Protein Therapies.

51. These plant closures and supply shortages garnered the national spotlight in 1997 and 1998. Congress held hearings on the safety of plasma-derivative protein therapy products, and the television program 60 Minutes produced a segment discussing Ig supply shortages.

52. This spotlight led directly to increased regulation of Plasma-Derivative Protein Therapy manufacturers. The FDA mandated that the industry implement various “good manufacturing procedures.”



53. Additionally, the FDA required that the industry monitor the distribution levels of Plasma-Derivative Protein Therapies. Pursuant to 21 C.F.R. § 600.81, the FDA required suppliers to provide the Center for Biologics Evaluation and Research (CBER), a division of the FDA, with bi-annual data regarding the distribution levels for all Plasma-Derivative Protein Therapies.

54. The International Plasma Products Industry Association (IPPIA), a trade association that represented industry manufacturers, voluntarily promised to submit *monthly* data to the FDA/CBER regarding distribution *and* inventory of Plasma-Derivative Protein Therapies for each of its members. The IPPIA promised to make aggregated data available to the public at large; competitor-specific data would be made available to the Center for Biologics Evaluation and Research.

**June 1999 Meeting Regarding Industry Supply Monitoring**

55. On June 17, 1999, the Blood Products Advisory Committee, an FDA/CBER committee, held a meeting in Rockville, Maryland to address supply and demand of plasma derivatives. FDA employees, industry representatives, and patient representatives attended.

56. Plasma manufacturers were represented at this meeting by Dennis Jackman. At the time, Mr. Jackman was the Vice-President of the IPPIA. Mr. Jackman currently serves as a Senior Vice-President at CSL Behring. As the Vice-President of the IPPIA, Mr. Jackman had access to distribution and inventory data for the entire industry, some of which he presented at the meeting.

57. Mr. Jackman was in attendance when the FDA presented company-by-company, month-by-month distribution data for 1998. The actual distribution figures for

individual companies were modified to preserve confidentiality, but someone with knowledge of each company's market share easily could determine each competitor's distribution totals.

58. Mr. Jackman emphasized the industry's desire to meet demand, stating: "Individual companies and members of our association . . . are going to seek to meet demand." However, the industry had to be very careful in how it went about meeting demand because of antitrust laws. Despite these hurdles, he stressed that "we are trying to collaborate in any way we can and cooperate by providing our monthly data." He further predicted that future supply would be "heavily impacted" by the industry's "investment in plant capacity and new processes."

59. Mr. Jackman's statements thus verbalized what would become a key component of Defendants' eventual strategy for restricting supply and increasing price in the marketplace: "collaborating" and sharing sensitive data regarding output and inventories.

60. This meeting also involved several detailed discussions regarding future demand for Plasma-Derivative Protein Therapies. From this meeting it became clear that the demand for Plasma-Derivative Protein Therapies—particularly Ig—had grown and would continue to grow.

61. Representatives from the Marketing Research Bureau, Inc. attended the meeting to discuss demand trends. The Marketing Research Bureau is an independent organization that monitors the plasma-derivatives market and provides Defendants and other manufacturers with regular reports related to distribution, price, and demand for plasma derivative products. The Market Research Bureau continues to provide the

industry—including Defendants—with annual reports detailing the demand for plasma-derivative products and pricing information across the industry.

62. At this meeting, the Marketing Research Bureau reported that the market for IVIG had seen “fairly steady growth” in the last 17 years. The market for IVIG in 1998 was 15.5 million grams, and the Marketing Research Bureau had estimated that the market in 2000 would be 18 million grams—a 16 percent increase. The Bureau emphasized that “demand is still growing.”

63. Manufacturers, including CSL and Baxter, were well aware of the growing demand for Plasma-Derivative Protein Therapies. According to remarks from a distributor at the meeting, executives from the plasma fractionation market estimated annual demand at 21 to 25 million grams for 1998, estimates well above those of other attendees.

64. Georgetown Economic Services also made a presentation at the meeting. The IPPIA contracted with Georgetown Economic Services to aggregate and average distribution and inventory data provided by the plasma manufacturers. Georgetown Economic Services continues to provide this service for the PPTA. (The PPTA is the current iteration of the trade organization representing industry participants that previously was known as the IPPIA).

65. Georgetown Economic Services reported its plan to assemble information to predict demand for plasma-derivative products over the next year, three years, and five years. To paint a picture of future demand, they intended to gather distribution data from the manufacturers, wholesalers, group purchasing organizations, and home health care

providers. Next, they planned to interview private and government scientists to assess future demand related to scientific breakthroughs and potential off-label uses.

66. This meeting laid the groundwork for several key components of Defendants' future conspiracy: Defendants' trade association began its inventory and supply data monitoring effort; the Marketing Research Bureau and Georgetown Economic Services announced plans to monitor future demand for the industry collectively; and Dennis Jackman was made privy to inventory and supply data for the major plasma manufacturers in the industry.

**Early 2000s: Increased Supply and Decreased Profits**

67. Between 2000 and 2003, once the Kankakee and Los Angeles facilities had resumed production, there was an oversupply of Plasma-Derivative Protein Therapies. This led to dramatic price declines and, in turn, to a 30% reduction in gross operating margins among producers. Because fixed costs represent a high proportion of the total costs of plasma protein production, this translated into a significant downturn in profits for the industry.

68. This period of excess supply, in turn, resulted in another significant change in the industry, causing the remaining producers to reduce production and plasma collection capacity and to begin in earnest to vertically integrate.

69. Notably, it was during this period of excess supply that Defendants' trade association, the PPTA, refined its data monitoring system and began exploring the parameters of the antitrust laws. (In 2000, the IPPIA merged with a similar trade association in Europe to become the PPTA.)

70. In 2001, the PPTA's President, Jan Bult, noted that because the plasma manufacturing industry was concentrated, it had to be especially careful of running afoul of the antitrust laws. He explained that the association had to walk a fine line to avoid antitrust liability. He asserted that the industry was "not allowed to facilitate information exchange among members which are focusing on the future situation. Of course, we are free to talk about what has happened and what is the retrospective data, but about future issues it's very difficult."

71. Mr. Bult reiterated how careful the PPTA and industry participants had to be when discussing supply data: "You can think you can be very creative and find ways to have public announcements and organize meetings and do it that way. It doesn't work. It doesn't work because there are statements that say these disclosures could be viewed as a means of signaling competitors so they can make plans based upon the activities of the other manufacturers. And we cannot do that."

72. Mr. Bult acknowledged that the PPTA's effort to gather current supply information from industry participants was of questionable legality. He admitted that *"Well, we had a discussion today about inventories. I just want to make you aware that we are at the edge [of] what we can do from a legal point of view."*

#### **September 2002: Launch Of "Light System"**

73. In September 2002, the PPTA launched a new data monitoring system that would allow manufacturers to monitor total industry output—and would become a key method for monitoring and regulating the conspiracy. The PPTA presented its "light system," which sought to warn industry participants when inventory levels of Plasma-Derivative Protein Therapies reached certain levels. Working closely with economists,

the PPTA identified ideal inventory to distribution “ratios” for the industry. Inventories were labeled “red” when approximately two weeks or less of inventory was available; “yellow” when two to five weeks of inventory was available; and “green” when greater than five weeks of inventory was available. Desired inventory levels were based on the ratio of the existing inventory on the first day of the month to the average distribution of a particular protein therapy over the previous 12 months.

74. Julie Birkofer, the Vice President of the PPTA, admitted that “these ratios were developed in very close consultation with economists and experts in the field of data collection and analyses.”

75. In a highly concentrated industry such as the Plasma-Derivative Protein Therapies industry, a monthly warning system that reports current inventory levels is the perfect mechanism to monitor competitor compliance with supply restrictions. However, when the system was first implemented, the PPTA did not represent all Plasma-Derivative Protein Therapies manufacturers; two manufacturers were not members. Therefore, the system was of limited utility when it was first implemented. But this would change shortly.

#### **Industry Consolidation**

76. In 1990, there were 13 producers of plasma-derivative protein products. In 2003, that number dropped to nine. Since 2005, there have been only five: CSL, Baxter, Talecris, Grifols, and Octapharma.

77. Several firms merged or were acquired. The large, integrated suppliers, most notably Defendants, have acquired numerous independent plasma collectors and facilities, and continue to do so. Soon after acquiring these facilities, Defendants shut down many of them in order to reduce supply.

78. CSL Limited acquired the Swiss Red Cross fractionator, ZLB, as well as 47 plasma collection centers from Nabi, in July 2000. It acquired Aventis Behring's plasma products business in 2003. CSL Limited subsequently closed 35 plasma collection centers in the United States, reduced plasma collections by 1 million liters, and reduced plant output by 1.1 million liters.

79. Baxter acquired Sera-Tec Biologicals LP in 2001 for the stated purpose of ensuring "[l]ong-term access to a consistent, stable supply of source plasma." In late 2002, Baxter acquired 42 plasma collection centers and a laboratory from Alpha Therapeutic Corporation (Mitsubishi Pharma). Baxter subsequently closed 26 of its own plasma collection centers and 38 collection centers that it acquired from Alpha Therapeutic, as well as a plasma manufacturing plant in Rochester, Michigan.

80. As one investment firm with knowledge of the industry has noted, "[a]bout 80% of the [plasma collection] centers are now owned by plasma-products companies such as Baxter International, CSL Limited, Grifols, and Talecris Biotherapeutics. This represents a complete reversal in ownership since 2000, when 80% of the centers were independent enterprises."

81. In 2005, a major non-profit entity, the American Red Cross, exited the plasma products industry. Baxter purchased the Red Cross's existing supply of plasma.

82. The plasma products industry as it now exists has significantly fewer suppliers than it did even six years ago. The remaining suppliers, most notably among them Defendants, are larger and more vertically integrated than ever before.

83. All five of the remaining plasma manufacturers are members of the PPTA. As members, they submit monthly distribution and inventory data to the PPTA as well as attend regular meetings.

### **THE CONSPIRACY**

84. As consolidation has occurred in the Plasma-Derivative Protein Therapies industry, supply has been limited in the face of increasing demand, and prices consequently have increased in recent years. GPOs, distributors, hospitals, physicians—and ultimately patients—have experienced tightening supplies and rising prices. Defendants' conspiracy to restrict supply and increase in prices for Plasma-Derivative Protein Therapies began on or about July 1, 2003 and has continued through the present.

85. The PPTA has played an integral role in facilitating information exchange between CSL and Baxter, explaining the economics of the industry, and gathering data to monitor Defendants' compliance with supply restrictions. Once Defendants restricted the supply of Plasma-Derivative Protein Therapies, the PPTA helped maintain the efficacy of the conspiracy by coordinating an effort to prevent a government declaration of a public health emergency due to supply shortages.

86. Baxter and CSL implemented their illegal agreement by coordinating and restricting output and by signaling to one other to do the same. Indeed, during and after the period of excess capacity earlier in the decade, Defendants recognized that controlling capacity was critical to preventing price competition and increasing profits.

87. A key component of the conspiracy was Defendants' focus on the prevention of oversupply of Plasma-Derivative Protein Therapies and plasma in the marketplace, as the firms were acutely aware that restrained output was profitable only if



they cooperated. CSL referred to this as the “*OPEC problem*,” explaining that “[w]hen capacity is greater than profit maximizing output levels, *there is a danger that a firm will ‘break ranks’ and chase market share, with the result that prices will fall.*” Baxter similarly has recognized that as long as competitors are not “*irrational*” and do not “*trash price and take share*,” they can increase supply steadily in line with market demand to keep prices high.

#### **Defendants Acquired Competitors To Reduce Output**

88. As early as 2003, CSL and Baxter began taking steps to control the supply of plasma products. CSL recognized the importance of doing so, listing as a “critical success factor” maintaining the supply/demand equilibrium and driving prices.

89. In particular, CSL and Baxter focused on preventing oversupply of IVIG and plasma. As a key part of this strategy, CSL and Baxter initiated the purchase of plasma donation and manufacturing facilities and promptly closed those facilities to limit supply.

90. Importantly, by 2003, Dennis Jackman had left his position at the PPTA to become a Senior Vice-President at CSL. In this position, he finally could implement the strategy, first laid out in 1999, of restricting supply and increasing prices by acquiring and closing collection and fractionation facilities.

91. In July 2003, Baxter announced plans to improve its plasma economics by reducing the amount of plasma collected and fractionated, and optimizing its supply. Baxter reported that it planned to reduce its total annual plasma production from 4.6 million liters to 4.0 million liters, a total reduction of about 13%. At that same time, Baxter also announced that it planned to close 26 plasma collection centers as well as its

Rochester, Michigan fractionation facility. This marked the beginning of Defendants' coordinated efforts to reduce supply.

92. Just a few months later, in December 2003, CSL announced that it had bought rival Aventis Behring. Initially, CSL described the acquisition as an opportunity for CSL to acquire synergies of operation. In February 2004, after the deal cleared key regulatory hurdles, CSL's managing director, Dr. Brian McNamee, stated that he believed full integration of the two companies could take 18 months, but predicted that benefits of the merger would be seen within a year.

93. CSL's acquisition of Aventis Behring became final on April 1, 2004. Immediately afterwards, CSL announced that it would reduce plasma input at its Kankakee facility (acquired in the deal) by 50% and that the Kankakee facility would cease production of three plasma products.

94. CSL admitted in federal court that the worldwide oversupply of Plasma-Derivative Protein Therapies prompted CSL to acquire Aventis Behring and reduce production at the Kankakee facility, contrary to CSL's reports before the deal closed. These admissions occurred in a suit unrelated to this action.

95. In 2004, soon after its acquisition of Aventis Behring, CSL set its sights on yet more consolidation in the industry and the effects that it believed "[o]ne further round of consolidation" would cause:

If the number of significant market participants were reduced from 5 to 4, and the new entity were to reduce capacity by 25% (*not atypical*), then:

1. The new entity would be more profitable than would be the aggregate of the separated firms (depending on the merger combinations). That is, the merged entity could appropriate some of the gains.

2. Market prices would rise soon after the capacity rationalisation.
3. The market would become less risky because the number of firms that profit by raising output would be reduced from 3 to 1 (or from 3 to two).
4. [CSL] would benefit as a participant in the merger, or as a bystander.

CSL further concluded that it was “less likely that a further [CSL] or Baxter acquisition (affecting the US market) would get FTC approval.”

96. Upon information and belief, CSL quickly turned to additional methods to help restrain supply. In 2004, *CSL destroyed plasma paste* on at least one occasion at its Kankakee manufacturing facility. Plasma paste is derived from plasma during manufacturing; it is an intermediate product before plasma can be manufactured into Ig or albumin. By destroying plasma paste, CSL limited the supply of Plasma-Derivative Protein Therapies.

97. That same year, on April 22, 2004, Baxter announced that it intended to further reduce plasma production by another 13% (or 400,000 liters). And in 2005, Baxter closed some of the blood collection facilities it had acquired when it purchased the American Red Cross’s plasma supply.

98. Defendants initially tried to downplay shortages resulting from their supply restrictions. In the summer of 2004, CSL informed one of its salespeople that it did not foresee a shortage of IVIG or albumin. But less than two months later, and shortly after a similar announcement from Baxter, CSL announced a shortage of IVIG and albumin. CSL gave its employees no advance warning of the shortage, which CSL and Baxter had intentionally precipitated, and provided pretextual explanations for the shortage.

### **The PPTA Helped CSL And Baxter Implement The Conspiracy**

99. As previously noted, CSL and Baxter are members of the PPTA. The PPTA is “the primary advocate for the world’s leading source plasma collectors and producers of plasma-based and recombinant biological therapeutics.” CSL and Baxter are Global, North American, and European Members of the association.

100. High-level executives from CSL and Baxter dominate the composition of the PPTA Board of Directors so that they effectively control the PPTA. Examples include:

- Peter Turner, President of CSL Behring, and Larry Guiheen, President of Baxter BioScience, serve on the association’s Global Board of Directors. Mr. Guiheen currently serves as the Board’s Chairman; Mr. Turner ended a four-year term as Chairman in 2007.
- Dennis Jackman, Senior Vice President of Public Affairs of CSL Behring, and Jean Marie Vlassembrouck, Vice President of Industry Affairs at Baxter, serve on the association’s Global Management Committee. Mr. Jackman chairs that committee.
- Robert Lefebvre, Vice President and General Manager of US Operations at CSL Behring, and Peter O’Malley, Vice President of Business Alliances at Baxter, serve on the association’s North American Board of Directors.
- Gordon Naylor, Executive Vice President of Plasma, Supply Chain, and Information Systems at CSL Behring, and Joe Rosen, Director of Business Development and Planning at Baxter BioLife, serve on the Source Board of Directors. Mr. Naylor currently serves as Chairman.
- Roland Martin, Senior Vice President and General Manager of CSL Behring, and Daniel Kenny, Vice President of Baxter BioScience Europe, serve on the association’s European Board of Directors.

101. The PPTA publicly laid out the economic rationale for Defendants' conspiracy and signaled to the industry's suppliers to restrict output. On August 26, 2004, the President of the PPTA, Jan Bult, gave a presentation to the Health and Human Services Advisory Committee on Blood Safety and Availability. At this presentation, Mr. Bult explained the economics of the plasma-protein business: if supply continued to increase, Defendants would not realize any profit, but if Defendants continued to control supply, prices (and profits) would rise.

102. CSL and Baxter had ready access to, if not approval over, Mr. Bult's presentation—senior executives from both companies serve as board members for the PPTA. Additionally, transcripts of the presentation, a slide presentation, and minutes from the meeting are available on the Health and Human Services website.

103. Mr. Bult opened his presentation by recognizing the economic perils the industry had faced and noting the need for change: ***“if we talk about long-term viability of this industry, we need to make economic adjustments. There is no other way around it.”***

104. The plasma-protein industry is, however, “highly concentrated” and therefore Mr. Bult warned that manufacturers must be “extremely sensitive to Anti-trust laws.” He explained that exchanging certain types of information was illegal and that ***“even when we would like to do it, we can't.”***

105. With that warning in place, Mr. Bult nonetheless proceeded to inform participants that a system was in place to give Defendants ready access to inventory levels. The system gathered data monthly and posted the results to a public website.

Although the system had been created in response to supply shortages in the late 1990s, Mr. Bult believed the monitoring system continued to serve an important purpose.

106. Following plasma-protein shortages in the late 1990s, Mr. Bult explained, the industry responded to consumer demand by increasing production. But in 2004 the industry faced a new dilemma. He noted that ***“The question now is do we have the right balance? In ’98 we had the situation where demand exceeded supply. Is that still the case? If we have increases in supply, is this balanced with demand or are we building and filling inventories?”***

107. To answer this question, Mr. Bult explained, one must understand the economics behind plasma manufacturing. According to Mr. Bult, manufacturing plasma into just one protein, like Ig or albumin, is not profitable—for revenue to exceed cost, a company must manufacture multiple proteins. Mr. Bult went on to explain that “the best revenue comes from the first liter of plasma that is manufactured and the further you get into the system the more problematic it becomes.” Thus, the more plasma protein manufactured, the less profit Defendants would realize.

108. Mr. Bult signaled to the plasma industry that the only way to maintain and increase profits was to limit supply: “[I]f there is any concern about immune globulins and, as I told you before, we don’t see a near-term threat for immune globulins, but you can ask the question why don’t you make more? Just make more so you can avoid all the problems. Well, if that is the case this is going to happen. You can make more but you can’t sell it. So you put it in inventory and also you get more albumin and it is still below your cost of manufacture. ***That leads to a situation where this industry is going to lose a significant amount of money and, as we have seen with the changes in the***

*marketplace, we are not in a position to do that. So, this will not happen, especially not if you look at the revenue that we have seen over the last years that has come down significantly.* All the changes that you see in the marketplace right now are a clear response to the economic pressures.”

109. He reiterated that “based on what we know today we do not see a near-term short supply,” but continued by signaling to suppliers what they should do going forward: “we will see—and that is my prediction—that individual companies, in response to their economic challenges, will tighten supply.”

110. After signaling that supply should be controlled, Mr. Bult ended his presentation with an ominous warning clearly intended for industry participants: “*We will continue to make the point that economic adjustments are needed* because look around and look at the companies that were in place in 1998—let me just give you a couple of examples, Alpha Therapeutics Corporation no longer exists. Biopharma has decided to divest and Baxter has significantly reduced its activities. Aventis Behring or Cention is now part of CSL. So, that is the reality. . . . [J]ust look around you and you will see what has happened as a result of the economic challenges.”

111. With this presentation, the PPTA President succinctly explained that the only way for Defendants to achieve acceptable profit margins was to restrict supply.

#### **Defendants Met Privately And Concealed Topics of Industry Meetings**

112. As a key part of the conspiracy, Defendants regularly met privately. Upon information and belief, CSL and Baxter exchanged information related to the supply and price of Plasma-Derivative Protein Therapies in the course of these private meetings. While Defendants regularly met at PPTA meetings, their contacts with each other did not

stop at the conclusion of those meetings. *After some of these meetings, Defendants gathered at bars for drinks or at restaurants for dinner away from the watchful eyes of association attorneys and other outsiders.*

113. At one recent meeting in Boston involving Defendants, Dennis Jackman expressed a desire for a better sense of the global supply of plasma-protein derivative products to be more accurate about the optimal production levels needed to maximize profits. *Mr. Jackman went so far as to suggest that the PPTA hire an economist to evaluate global demand for Plasma-Derivative Protein Therapies and collectively determine the exact amount of supply each manufacturer should produce to achieve the greatest profit overall.*

114. Defendants have taken steps to conceal the anticompetitive elements of their conversations and meetings. *Minutes from PPTA meetings, including the July meeting in Boston, are routinely “scrubbed” to remove references to any topic of conversation that potentially violated antitrust laws.*

115. Defendants also gathered regularly for the stated purpose of discussing proposed industry regulations. Throughout 2008, executives from CSL and Baxter, as well as other suppliers, gathered monthly with the IDF. These meetings took place at either the IDF headquarters or the offices of the manufacturers’ lobbyist firms.

116. The stated purpose of these meetings was to develop legislation to restore access to IVIG supply to hospitals, homecare, and other sites that used the product. But conversation routinely shifted to different, inappropriate topics.

117. Top executives from the industry attended the IDF meetings, including, but not limited to: Dennis Jackman, Senior Vice President of Public Affairs for CSL; Deb



Williams, a lobbyist for Baxter; and Peter O'Malley, President of Baxter's Bioscience division. As previously noted, both Mr. Jackman and Mr. O'Malley also serve on PPTA boards.

118. Executives from smaller, non-colluding manufacturers of Plasma-Derivative Protein Therapies have voiced concerns that they believe CSL and Baxter overstepped the bounds of antitrust laws by discussing the supply and pricing of Plasma-Derivative Protein Therapies at PPTA and other industry meetings.

### **Baxter And CSL Signaled Each Other To Reduce Supply**

119. Yet another aspect of Defendants' conspiracy involved Baxter and CSL signaling each other to keep supply under control.

120. Competitive information is widely available from industry sources and the competitors themselves. Firms closely monitor each other's activities with respect to plasma collection, manufacturing, and output, and firms collect and catalogue an extraordinary wealth of timely competitive information.

121. For example, CSL executives told employees at town-hall meetings that they kept track of their competitors' information, in part by monitoring 10-K filings.

122. Defendants have taken advantage of this timely competitive information by engaging in signaling—*i.e.*, the intentional sharing of competitive information for purposes of seeking to ensure that manufacturers all are restraining output, curbing growth, and maintaining high prices.

123. In particular, Defendants have used specific key words to: (1) suggest to each other that increasing the production of Plasma-Derivative Protein Therapies could hurt the firms' ability to reap significant profits that they all gained during an extended

period where demand exceeded supply for these products; (2) remind each other of how, during a period when supply increased, prices and profitability for firms dropped substantially; and (3) encourage one another to increase supply only incrementally to keep pace with demand, and not increase supply to the extent the firms actually compete with one another for market share.

124. Baxter's CFO acknowledged Defendants' signaling in a recent investor call: "Why any of us would, for a very short-term gain, do anything to change [the current marketplace dynamics], I just don't see why we would. It wouldn't make any sense and *from everything we read and all the signals we get, there is nothing that says anyone would do that. I think people are very consistent in the messages they deliver, which are pretty consistent with what we have told you today.*"

125. Baxter's CEO has also noted that: "it would seem that people [competitors] are doing what they need to do to ensure that the global demand can be met collectively by the industry." Despite increasing demand for these products, he stated that, "*we're going to see or promote total market perspective, growth, and volume of the highest single digits and growth in price of low to mid-single digits longer term.*"

126. Similarly, CSL Behring's President, Peter Turner, has publicly signaled that CSL Behring would not dramatically increase its manufacturing of Plasma-Derivative Protein Therapies, despite allegations of supply shortages. Mr. Turner stated: "In terms of 2005-2006, we will have a similar supply to the last 12 months plus we hope to have a new product, which is a subcutaneous immune globulin infusion." Although Mr. Turner acknowledged some supply shortages stating, "I accept that supply may be tight, certainly tighter than it's been in recent years," he confirmed that CSL Behring's

manufacturing levels would remain relatively stable, stating that “if you look at the status quo, we will continue to supply the equivalent volume that we've been supplying to the U.S. market.”

127. And notably, one month after the filing of Plaintiff's initial complaint, CSL signaled to its competitors that the price increases facilitated by Defendants' conspiracy were about to end. Brian McNamee, CEO of CSL, told Bloomberg news that CSL would not raise prices in the coming year and in fact might lower prices.

**Supply Restrictions Did Not Result From Natural Market Forces**

128. The restriction of supply and increase in prices did not result from natural market forces. Rather, they were caused by Defendants' conspiracy, which Defendants formed in response to the excess supply and decreased prices that occurred earlier in the decade and that Defendants did not want to experience again.

129. Defendants' coordinated acquisition and closure of collection and fractionation plants are not consistent with free competition. Because demand for Plasma-Derivative Protein Therapies grew throughout the Class Period, Defendants would have been irrational to restrict supply absent an illicit agreement that included assurances that both leading manufacturers would do so. Otherwise, one Defendant's supply restrictions merely would have provided an opportunity for the other to increase production and expand its market share, thereby increasing sales volume and revenue.

130. In moments of candor, Defendants have admitted that supply shortages did not result from insufficient plasma donation. Although Defendants told patient advocates that shortages were caused by a lack of volunteer donors, they told their investors otherwise. During one investor call, Baxter CEO Bob Parkinson responded to a question

about the cause of reduced plasma supplies by stating that he did not “believe that the number of people coming forward willing to donate plasma necessarily ha[d] any impact relative to overall supply.” Furthermore, Rob Davis, VP and CFO of Baxter explained that the “bottleneck” existed not at the collection end, but rather at the manufacturing centers.

131. According to a major distributor of Plasma-Derivative Protein Therapies, distributors began to see “a tightened supply trend” around October of 2003 and throughout that year, “[s]upply was gradually, almost imperceptibly starting to tighten.” This same distributor attributed difficulties in obtaining IVIG to the “new market reality—fewer suppliers and rising prices.”

#### **Defendants’ Conspiracy Caused A Public Health Crisis**

132. Defendants sought to maintain the supply of Plasma-Derivative Protein Therapies just below demand to keep prices high. Defendants’ coordinated supply restrictions were implemented, however, during a period of growing demand for these therapies, and as a result, there was insufficient supply to meet patients’ needs. Insufficient supply, in turn, caused patients, doctors, and patient advocates to urge the government to declare a public health emergency.

133. Patients, physicians, and insurance companies first began reporting supply shortages of plasma-derivative protein therapies in 2005—approximately one year after Defendants completed their efforts to close plasma collection and manufacturing facilities. As previously explained, it typically takes between seven months to one year to manufacture plasma into Plasma-Derivative Protein Therapies. Thus, one would expect to see the full effects of Defendants’ efforts to control supply in 2005 and 2006.

134. In 2005, the IDF conducted a survey of physicians to assess the scope of Ig shortages that patients and physicians had been reporting. According to that survey, 33% of responding physicians reported significant difficulty obtaining IVIG products for their patients. Physicians also reported that 40% of their patients had suffered adverse health effects due to problems accessing sufficient Ig supply.

135. Insurance companies began noticing supply shortages (and increased prices) in 2005 as well. That year Kaiser Permanente informed patients that due to “an acute nationwide shortage of IVIG due to pharmaceutical manufacturing shortages” it could not cover patients’ IVIG treatment.

136. By 2006, supply shortages of Plasma-Derivative Protein Therapies, particularly IVIG, had caused a crisis in the patient community. Patients and doctors, along with a bipartisan coalition of 55 members of Congress, asked the Secretary of Health and Human Services (HHS) to declare IVIG shortages a public health emergency. The HHS Committee on Blood Safety and Availability joined this coalition in urging the Secretary to declare a public health emergency, stating “there is a worsening crisis in the availability of and access to IGIV products that is affecting and placing patients’ lives at risk.”

137. Defendants’ supply restrictions led directly to the rationing of Plasma-Derivative Protein Therapies to purchasers. In 2006, HHS investigated reports that patients were experiencing problems purchasing IGIV. HHS stated that *“[m]anufacturers are currently allocating IGIV to their customers. Under this allocation system, most customers are expected to justify their current IGIV use to the manufacturer to maintain and/or increase their allocations. In economic terms,*

*current IGIV supplies are being rationed.*” HHS also noted that “[t]he existence of a secondary market with high IGIV prices combined with a manufacturer instituted allocation system for IGIV are symptomatic of a market in which demand exceeds supply.” HHS concluded that a majority of hospitals surveyed could not purchase enough IGIV to meet all of their patient needs, and calculated that the shortfall of supply relative to demand was approximately 14%.

138. Indeed, participants across the industry reported supply shortages of Plasma-Derivative Protein Therapies. According to one GPO, the industry would collect 3 million fewer units of plasma in 2006 for the purpose of making plasma-derivative products such as IVIG. A representative from another GPO noted that “the market is certainly tight” and explained that distributors were forced “to manage inventories to the gram level.”

139. The effects of these supply shortages were not limited to one geographic area. According to the IDF, patients and doctors in almost every state had reported inadequate IGIV access.

140. Defendants’ conspiracy resulted in critically low supplies of Plasma-Derivative Protein Therapies that caused many patients to go without crucial treatments. According to a survey of hospital pharmacies administered by the IDF in 2006, 32% of hospitals had turned away patients seeking Ig. Similarly, 57% of physicians surveyed reported that they had been unable to provide patients with adequate amounts of Ig during the first quarter of 2006. According to the same survey, 100% of the distributors asked responded that they had been unable to obtain extra Ig from manufacturers.

141. As a result of Defendants' supply restrictions, patients were forced to go without Plasma-Derivative Protein Therapies. Some patients reportedly suffered side-effects from alternative treatments and infections caused by delayed treatment. In some instances, patients reportedly died when they had to wait too long to receive treatment. The difficulties faced by patients experiencing IVIG access problems is perhaps best summarized by one patient from Florida who said, in a statement to the IDF, "It's disgusting. What do they expect us to do? Are we supposed to just get sicker and sicker until we pass away?" Another patient from Missouri called the IDF, stating "I am an 81 year old Medicare PID [primary immunodeficiency disorder] patient . . . I am sick all the time, and am not sure if I will be able to live long enough to get my next infusion. I had an infusion scheduled at the hospital. As I was leaving for the hospital, they called to cancel my appointment. They told me that they will not be able to infuse me." These are but two representative statements out of hundreds from patients who contacted IDF to report problems obtaining Plasma-Derivative Protein Therapies.

142. Medicare patients suffered from supply shortages of Plasma-Derivative Protein Therapies at a disproportionate rate compared to privately insured patients. According to a survey conducted by the IDF, twice as many Medicare patients as privately insured patients encountered problems obtaining Ig between 2003 and 2006.

143. Yet privately insured patients were not left unaffected. Many were denied treatment when supplies ran out. As stated by one distressed father from Ohio after his son's appointment to receive IVIG was canceled, "my family is covered by Anthem BCBS, which I thought was good insurance. How can something like this happen?" And, according to the IDF, 50% of private insurance companies paid at, or below, the

Medicaid rate for Plasma-Derivative Protein Therapies, forcing patients to pay the difference or denying coverage altogether.

144. Another element of Defendants' conspiracy involved the systematic refusal to sell Plasma-Derivative Protein Therapies at federally mandated discounted prices. Hospitals serving disproportionate numbers of Medicaid patients are entitled to front-end discounts on drugs under Section 340B of the Public Health Service Act (created under Section 602 of the Veterans Health Care Act of 1992).

145. Hospitals eligible for 340B discounts were routinely informed that there was insufficient supply of IGIV to fill orders. According to a survey of eligible hospitals conducted by the Public Hospital Pharmacy Coalition, only 21.42% of responding hospitals had been able to obtain IGIV at the discounted price—in other words, nearly 80% of eligible hospitals were denied access at the discounted price. However, 68.22% of eligible hospitals had been able to fill orders at prices higher than the discounted rate.

**Defendants Publicly Deny Supply Shortage, Over-report Industry Supply,  
And Blame Medicare**

146. A key aspect of Defendants' conspiracy involved concerted attempts to dissuade HHS from declaring a public health emergency. Defendants' executives, particularly Dennis Jackman, had learned from the events of the late 1990s and knew that declaration of a public health emergency would likely lead to an invasive government investigation into the industry and efforts to increase supply.

147. Defendants employed two primary strategies to dissuade HHS from declaring a public health emergency (and thus prevent an industry investigation): (1) Defendants, via the PPTA, denied supply shortages and significantly over-reported the actual supply of Plasma-Derivative Protein Therapies in the industry, and (2) Defendants,

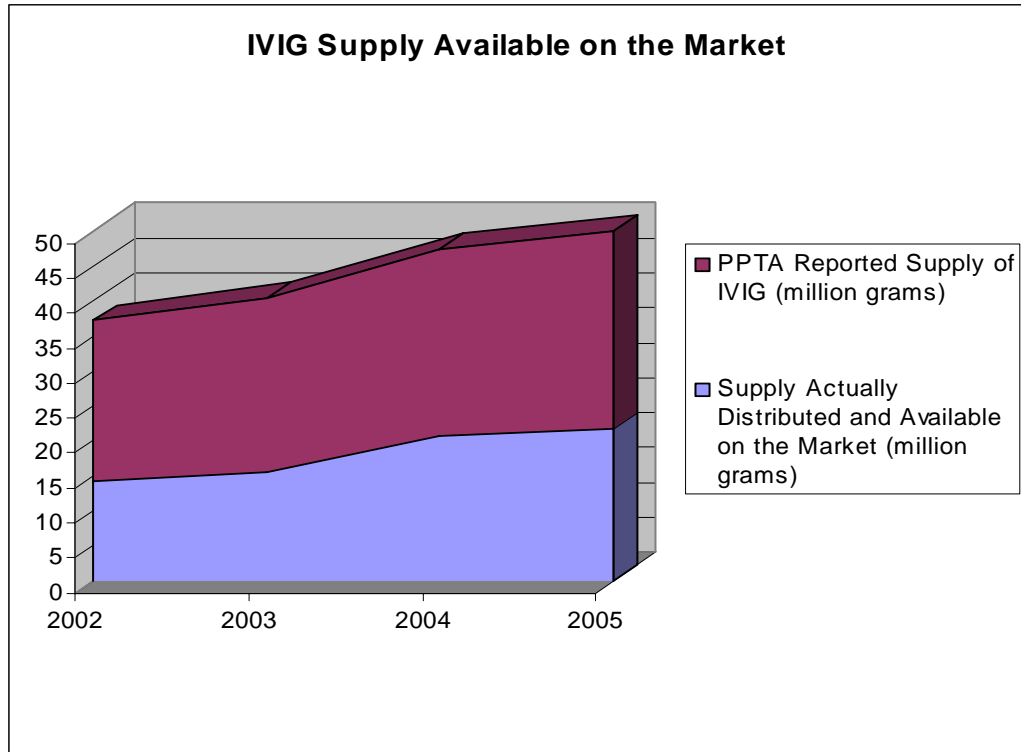


again via the PPTA, sought to shift the focus away from reports of a supply shortage by focusing on Medicare reimbursement rates as the purported sole cause for patients' access problems.

148. Despite the inability of purchasers to obtain sufficient supply, Defendants steadfastly denied the existence of a supply shortage. The most striking example of Defendants' cover-up involves the supply of IVIG. Throughout 2006 and 2007, HHS investigated claims of an IVIG shortage. In response to this investigation, the PPTA provided HHS with data regarding the supply of IVIG available for distribution. As part of this same investigation, an independent company, IMS Health, also evaluated the amount of IVIG available for distribution. *According to the 2007 HHS report, the PPTA reported nearly twice as much IVIG available for distribution as did the independent agency.*

149. Three explanations were proffered for this discrepancy: rounding error; exports; and manufacturer and distributor inventories. The unlikelihood of a rounding error accounting for a 30 million gram difference in reported data is self-evident. And the PPTA verified that the submitted data did not include exported IVIG. The only plausible explanation is that Defendants restricted supply to manipulate prices and then misreported this supply to HHS to avoid a public health emergency declaration.

150. The following graph illustrates the difference in the amount of supply PPTA reported compared with what was actually available on the market:



151. In this instance, the PPTA's data monitoring system served as an effective means of concealing Baxter and CSL's supply restrictions. By establishing a regular supply monitoring system, the PPTA was perfectly poised to help conceal supply limitations.

152. Defendants took steps to shift government and patient attention away from reported supply shortages. Defendants did this mostly by focusing the debate on an easy enemy: Medicare reimbursement rates. Defendants misleadingly blamed patients' inability to obtain sufficient amounts of Plasma-Derivative Protein Therapies on the failure of Medicare reimbursement rates to keep up with the price for these therapies.

153. Julie Birkofer, Vice President of the PPTA, made numerous presentations to HHS advocating for new Medicare reimbursement formulas to compute plasma protein reimbursement rates.

154. Defendants told the IDF and other patient-advocacy groups not to discuss allegations from physicians and patients that a supply shortage existed and instead to focus only on problems related to Medicare reimbursements. This included efforts on the part of Defendants to encourage the IDF not to report physician survey data verifying their allegations of a supply shortage. Similarly, on at least one occasion, Defendants actually censored a patient advocate's presentation in an effort to keep advocates on-message and off the topic of supply shortages. Defendants edited advocate messages to eliminate any implications that the industry was acting collectively regarding IVIG supply or that patients or GPO's were unable to obtain sufficient supply.

155. By denying supply shortages and shifting focus away from supply and onto Medicare, Defendants managed to avoid the declaration of a public health emergency. Defendants thus maintained their conspiracy by preventing a likely invasive government investigation into the industry, which likely would have resulted in efforts to increase supply and reduce the impact of Defendants' conspiracy.

#### **Defendants Monitored The Conspiracy Using PPTA Data**

156. The PPTA's data gathering effort allowed Defendants to monitor each other's compliance with agreed-upon supply restrictions, and thus allowed Defendants to police their conspiracy. Indeed, as CSL's Chief Economist has remarked in the context of Defendant's efforts at monitoring supply and demand, *"economics can help [us] understand how to loosen the shackles of competition."*

157. From their inception, the industry's data gathering efforts pushed the limits of the antitrust laws. Although the exchange of past supply and price information

can facilitate competition, the industry's efforts focused on the gathering of *current* supply information, which is far more problematic from an antitrust standpoint.

158. When the industry first implemented its data monitoring system in the late 1990s, the industry consisted of 13 different companies, two of whom were not members of the trade association. Because there were more participants submitting data, and some who were not submitting data, the aggregated data could not easily be used as a tool to monitor individual competitors' production.

159. But as the industry consolidated, the aggregated data collected by the PPTA represented fewer companies, making it far easier for any individual company to assess what proportion of the data came from which company. Indeed, since Baxter and CSL each possessed more than 25% of the market shares of both Ig and albumin (Baxter has 35.4% of the Ig market and 36.44% of the albumin market; CSL possesses 27.5% of the Ig market and 36.61% of the albumin market), the data reported by the PPTA could be easily attributed to specific suppliers. Because this data can easily be attributed to individual suppliers, it provides an effective means for Defendants to monitor compliance with supply restrictions.

**Defendants Pressured Smaller Competitors Not To Appreciably Increase Capacity**

160. Defendants have explored means of punishing firms, most notably Talecris, that have attempted to buck the prevailing restrained industry approach by increasing output.

161. Baxter and CSL closely monitor each other, collecting and cataloguing an extraordinary wealth of timely competitive information, to ensure that all suppliers are engaging in desired "*rational*" and "*disciplined*" behavior. According to the FTC, *CSL*

*and Baxter even have explored means of punishing firms that dare to “‘break ranks’ and chase market share.”*

162. According to the FTC, Talecris is “the one firm that has consistently and significantly expanded output in the United States.” Statements from Defendants’ files corroborate this, noting that Talecris “has significantly and consistently increased production and U.S. supply year after year—more than any other manufacturer,” and that it planned to continue to do so in the coming years.

163. Talecris stated in a 2008 SEC filing that it “intend[ed] to serve the overall market growth with incremental increases in production capacity” in 2008 and 2009. And before agreeing to CSL’s planned acquisition, Talecris planned to be responsible for 45% of the industry’s future output expansion over the next two years—a business strategy CSL labeled “*irrational*.”

164. Talecris’s business strategy thus was at odds with Defendants’ conspiracy to restrict supply, subjecting it to punishment by CSL and Baxter.

165. Not surprisingly, in the words of Cerberus-Plasma Holdings LLC (Talecris’ majority shareholder) executives, *CSL was “truly scared that Talecris might actually succeed with its planned center expansion” and the consequent increase in output*. Cerberus executives further remarked that *CSL executives were “worried . . . that [Talecris’] expansion will have a negative effect on the market as a whole.”*

166. Indeed, without the aggressively expanding Talecris, Baxter and CSL, the only two remaining significant producers of Protein-Derivative Plasma Therapies, more successfully and completely could control industry output. As CSL’s Chief Economist

remarked, an “[i]ncrease in industry concentration should make price stability and/or price increases easier to sustain” because “*competition erodes rents.*”

167. CSL’s fear of the price-reducing effect that Talecris’ planned expansion would have in the market provided motivation for CSL’s attempted acquisition of Talecris and the significant premium that CSL agreed to pay in 2008—about \$800 million more than it was willing to pay in 2007. Consequently, in a further attempt to reduce industry production capacity and maintain high prices and margins, CSL Limited attempted to acquire Talecris.

168. In an unusual move for a company whose competitor was contemplating a key acquisition, Baxter publicly expressed its view that CSL Limited’s attempted acquisition of Talecris would be “*a positive stabilizing move within the industry.*” The FTC subsequently filed suit to block the attempted acquisition. (The FTC action is discussed below.)

169. In contrast to Talecris, the remaining competitors in the industry, Grifols and Octopharma, are too small to have a significant market impact. In high-level, internal communications, Talecris executives discussed this issue: “[S]o really the question is whether grf [Grifols] and octa[pharma] would trash the market. And they’re not big enough to strongly shock supply. . . .”

170. Defendants’ agreement to restrict supply and raise prices has been assisted by increased industry consolidation and the resulting oligopolistic market structure. The remaining participants have recognized that they are operating in an oligopoly where they are better off avoiding competition, restricting supply, and raising prices. Defendants’

unlawful signaling has aided and reinforced this recognition on behalf of industry participants.

### **Defendants' Conspiracy Has Worked**

171. Defendants' conspiracy has worked, causing Plaintiff and other Class members to purchase Plasma-Derivative Protein Therapies at supra-competitive prices. Beginning in July 1, 2003 and continuing through the present, prices for Plasma-Derivative Protein Therapies stabilized and then consistently increased.

172. The average sales price for a gram of IVIG has increased from about \$47.60 in 2005 to about \$57 in 2009, according to an analyst presentation that Grifols gave on March 5, 2008. The same presentation stated that "IVIG, which remains the driver of the plasma derivatives market, has witnessed price increases since 2005, coinciding with increased demand related to product availability."

173. The average sales price for a gram of albumin has increased from about \$1.25 in 2005 to about \$2.20, according to the same Grifols presentation. The presentation also reports that "average albumin prices have steadily increased since 2005 from U.S. \$14 to around U.S. \$35 per 12.5 g. vial at present." A Talecris 2008 SEC filing similarly notes that "[p]rices for albumin have increased significantly since 2005 . . . . The average selling price in 2007 was \$28.55, having grown at a CAGR of 35% since 2005, when the U.S. average selling price (ASP) was \$15.58."

174. CSL's and Baxter's contemporaneous business reports have borne out these facts. For example, CSL Limited reported in its October 2004 Annual General Meeting presentation: "IVIG - prices have been stable with upward pressure going forward; currently experiencing solid demand;" and "Albumin - prices stable after period

of weakness; inventory oversupply reducing.” In its October 2005 Annual General Meeting presentation, CSL Limited remarked that “US IVIG pricing environment improving,” and that with respect to CSL Behring, it is “managing plasma throughput to match: run down in inventory benefit; reduction of inventory levels; [and] demand.” The Chairman’s Address from the same 2005 meeting stated that CSL “Behring is well positioned to develop its global business through,” among other things, “an effective balance between supply and demand.” And in its October 2006 Annual General Meeting presentation, CSL Limited noted both that the “strong global demand for plasma therapies continues,” and “plasma sector stability.”

175. Defendants’ conspiracy has resulted not only in supra-competitive pricing, but also extraordinary profits for CSL and Baxter, even as most other industries have experienced drastically lowered earnings in the face of the global economic crisis.

176. According to a March 2009 report issued by CSL’s chairman, CSL experienced a post-tax net profit of \$502 million for the half-year ended December 31, 2008, an increase of 44% from the same period the previous year. The report also notes that “[t]he global financial crisis has had little to no impact so far on sales of CSL’s portfolio of life-saving therapies and essential vaccines . . . [a]nd we anticipate broadly stable market conditions to continue.”

177. CSL Behring’s sales revenue increased 33% to \$1.8 billion compared with the same period the previous year, “with strong contributions from both core and specialty plasma products,” according to the same March 2009 CSL report.

178. Revenues from Baxter’s BioScience unit climbed 12% to \$1.36 billion in 2008, largely due to sales of plasma-based hemophilia and immune disorder treatments,



vaccines and biosurgery products. Due to the profit its BioScience unit has generated, one news article has noted that “Baxter is one of a handful of stocks that have proven somewhat resistant to the global recession.”

### FTC INVESTIGATION

179. On March 27, 2009, the FTC authorized a lawsuit to block CSL Limited’s proposed \$3.1 billion acquisition of Talecris, charging that the deal would be illegal and substantially would reduce competition in the United States markets for Ig, albumin, Rho-D, and Alpha-1. On the same day, the FTC also sought a preliminary injunction in federal district court in the District of Columbia to stop the transaction pending completion of an administrative trial.

180. In an FTC press release accompanying the filing of the lawsuit, Richard Feinstein, Director of the FTC’s Bureau of Competition, stated that “[s]ubstantial consolidation has already occurred in the plasma protein industry, and *these highly concentrated markets are already exhibiting troubling signs of coordinated behavior.*”

181. The FTC described in its complaint, among other things, “*troubling signs of coordinated behavior,*” including Defendants’ signaling, product rationing, and other statements and actions by Defendants indicative of anticompetitive conduct.

182. The FTC alleged that, “with the elimination of Talecris—the one firm that has consistently and significantly expanded output in the United States—*CSL and Baxter International, Inc. (“Baxter”)* would face no remaining significant obstacle in their efforts to coordinate and tighten supply conditions for the relevant products, to the great detriment of consumers.”

183. The FTC has stated that language contained in documents of CSL and Baxter suggests *a strong possibility of ongoing coordinated interaction between firms in the plasma industry*. Evidence of transparency, interdependence, and signaling among firms is particularly relevant to the allegations in this matter. The language at issue bears on these very important points, and demonstrates how firms used specific key words to:

- suggest to each other that increasing the production of lifesaving drugs could hurt the firms' ability to reap the significant profits they all achieved during an extended period where demand exceeded supply for the key products;
- remind each other of how, during a period when supply increased, prices and profitability for the firms in the market dropped significantly; and
- encourage each other to only increase supply incrementally to keep pace with demand, not increase supply to the extent the firms actually compete with each other for market share.

184. The FTC also has noted that the “*quoted language*” in its complaint taken from the files of Baxter and CSL “*is similar to language that in other instances has been found to be evidence supporting an illegal price fixing conspiracy*. See, e.g., In re High Fructose Corn Syrup Antitrust Litigation, 295 F.3d 651, 662 (7th Cir. 2002) (Posner, J.) (referring to competitor as a ‘friendly competitor,’ mentioning an ‘understanding between the companies that . . . causes [them] not to . . . make irrational decisions,’ and querying whether competitors ‘will play by the rules (discipline)’ can all be evidence of an explicit agreement to fix prices).”

185. The FTC has recognized that some of the language from the files of CSL and Baxter would cause them “*embarrassment*” and “*could ‘expose [CSL] to possible treble damages actions.’*”

186. Shortly after the filing of the FTC complaint, on June 8, 2009, CSL Limited and Talecris publicly announced that they would abandon their proposed merger. On June 15, 2009, the FTC and the two firms jointly filed a motion to dismiss the FTC's complaint on that basis, and on June 22, 2009, the FTC dismissed the complaint.

### **MARKET CHARACTERISTICS**

187. The structure and characteristics of the Plasma-Derivative Protein Therapies markets in the United States are particularly conducive to a price-fixing agreement, and have made collusion particularly attractive in this market. These factors are discussed below.

#### **Commodity-Like Products**

188. A commodity-like product is one that is standardized across suppliers and allows for a high degree of substitutability among different suppliers in the market. When products offered by different suppliers are viewed as interchangeable by purchasers, it is easier for the suppliers both to agree on prices for the product and to monitor these prices.

189. Plasma-Derivative Protein Therapies are homogeneous, commodity-like products within a given product category (*e.g.*, Albumin or Ig), and one Defendant's Plasma-Derivative Protein Therapies easily can be substituted for corresponding products made by the other Defendant. Indeed, Talecris noted in a 2008 SEC filing that "[a]mong albumin products, competition is generally based on price, given that the products tend to be homogeneous."

190. Because Plasma-Derivative Protein Therapies are commodity-like products, purchasers make purchase decisions based predominantly, if not entirely, on price.

#### **Lack of Substitutes**

191. The lack of available substitutes for a product also helps facilitate an effective price-fixing conspiracy. Without substitutes, producers of the product can raise prices without losing significant sales to closely competing products.

192. For hospitals, physicians, and others that use Plasma-Derivative Protein Therapies, there simply are no suitable substitutes for these products, at any price. They must purchase Plasma-Derivative Protein Therapies regardless of the price; nothing else will do. Indeed, as Patrick Robert of the Marketing Research Bureau Inc. has noted, “therapeutic plasma proteins [including Plasma-Derivative Protein Therapies] remain essential life-saving drugs for which there is still no competitive drug.”

#### **Industry Concentration**

193. A high degree of concentration facilitates coordination among co-conspirators.

194. Defendants control a high percentage of the United States plasma-derivative protein industry, collectively possessing about a 60% market share. In particular, Baxter controls about 36% of the market, and CSL controls about 24% of the market. The remaining manufacturers, Talecris, Grifols USA (“Grifols”), and Octapharma USA, Inc. (“Octapharma”), possess shares of approximately 23%, 7% and 5%, respectively. Defendants’ collective shares of the Ig and Albumin markets are even higher than their shares of the overall plasma-derivative protein industry.

195. With respect to the domestic Ig market, according to 2008 sales volumes, Defendants collectively possess approximately a 62.9% market share. CSL has about a 27.5% market share, and Baxter has about a 35.4% market share. The remaining manufacturers, Talecris, Grifols, and Octapharma, possess shares of approximately 20%, 9% and 7.2%, respectively. The market is highly concentrated, with a Herfindahl-Hirschman Index (“HHI”) of 2,579. (The HHI test is used by the FTC and DOJ to gauge market concentration. An industry with an HHI exceeding 1,800 is deemed “highly concentrated.”)

196. With respect to the domestic albumin market, according to 2008 sales volumes, Defendants collectively possess approximately a 73.05% market share. CSL possesses about a 36.61% market share, and Baxter maintains about a 36.44% share. The remaining competitors, Talecris, Grifols, and Octapharma, possess shares of 8.83%, 13.06%, and 5.07%, respectively. The market is highly concentrated, with an HHI of 2,942.

197. Throughout the Class Period, Defendants collectively possessed market power to raise prices above competitive levels in the Plasma-Derivative Protein Therapies markets in the United States without losing appreciable market share to non-conspirators.

#### **Barriers to Entry**

198. The presence of significant entry barriers to potential competitors that could otherwise cause the incumbents to reduce their prices helps facilitate coordination among co-conspirators.

199. The market for Plasma-Derivative Protein Therapies is characterized by high entry barriers. No firm has entered *de novo* in recent history, and prospective entrants have little chance of making a meaningful market impact in a timely fashion.

200. By CSL's own admission, there are "immense barriers to entering the market" for Plasma-Derivative Protein Therapies. Furthermore, CSL identifies "significant barriers to entry" as one of the six "key characteristics of the Ig market," and notes that there is "[n]o realistic prospect for an increase in the number of firms." Talecris agrees, noting that "significant regulatory, IP, and capital barriers to entry mitigate the threat of new competitors as well as capacity increases for several years."

201. Each step of the manufacturing process for Plasma-Derivative Protein Therapies involves substantial up-front, sunk costs; onerous and lengthy regulatory approvals by federal and state agencies; and specialized technical know-how and expertise.

202. Entry into the Plasma-Derivative Protein Therapies markets also requires a significant amount of intellectual property, including trade secrets relating to purification of products and pathogen safety, and substantial product research and development.

203. Regulatory hurdles impose significant barriers to entry and extend the time it would take to enter the United States markets, let alone make a significant impact in the markets.

204. In addition, the construction and maintenance of production facilities, including regular improvements necessitated by evolving standards of manufacturing practices, require extensive capital expenditures and may involve long lead times to obtain the necessary governmental approval.

205. Any new competitors in the United States also would need to secure an adequate supply of domestic plasma, because only plasma collected in the United States is certified for use in products sold domestically. Because there currently are only a very limited number of independent plasma suppliers, most of whose plasma collection and center development capacity is already contracted to existing manufacturers, any new competitor likely would have to develop its own domestic-based plasma collection centers and related infrastructure.

#### **Demand Inelasticity**

206. Price elasticity of demand is the measure of responsiveness in the quantity demanded for a product as a result of change in price of the same product. Inelastic demand is a market characteristic that facilitates collusion, allowing producers to raise their prices without triggering customer substitution and lost sales revenue. Inelastic demand is another indicator that a price-fixing conspiracy would be successful.

207. The demand for Plasma-Derivative Protein Therapies is highly inelastic. Plasma-Derivative Protein Therapies are considered medical necessities that must be purchased by hospitals, physicians, and others at whatever the cost. Moreover, there are no close substitutes for these products.

#### **Opportunity for Conspiratorial Communications**

208. Defendants are members of trade associations, such as the PPTA and the IDF, and regularly attended meetings together and meet privately before or after these meetings.

209. As previously noted, the PPTA is “the primary advocate for the world’s leading source plasma collectors and producers of plasma-based and recombinant

biological therapeutics;" Baxter and CSL are Global, North American, and European Members of the association; and no purchasers or patient advocacy groups count themselves as members of this association.

210. The PPTA convenes its annual meeting, known as the Plasma Protein Forum, in June in the Washington, D.C. metropolitan area, and high-level executives from Defendants, such as Messrs. Turner and Guiheen, routinely attend. The PPTA also holds regular conferences such as the PPTA Business Forum, which took place in New Orleans, Louisiana on October 25, 2009.

211. Defendants also gather regularly for the stated purpose of discussing relevant regulation, providing Defendants with an opportunity to share information.

212. As previously discussed, in 2008 executives from CSL and Baxter gathered monthly with the IDF for the stated purpose of developing legislation to restore access to IVIG supply to hospitals, homecare, and other sites.

213. Such meetings provide the opportunity for participants in anticompetitive conspiracies such as this one to meet, have improper discussions under the guise of legitimate business contacts, and perform acts necessary for the operation and furtherance of the conspiracy.

214. Defendants also used private analysts as go-betweens to swap competitive information about their stock of plasma-protein supplies. Analysts regularly called Defendants to ascertain supply levels because supply closely correlated to price in the plasma-protein derivative market. After having spoken with one Defendant, analysts would call the other Defendant, and relay supply information.



215. Moreover, Defendants use the same market research firm, the Marketing Research Bureau, to estimate future demand for Plasma-Derivative Protein Therapies and to monitor pricing trends.

### **ANTITRUST VIOLATIONS**

216. Beginning at least as early as July 1, 2003, and continuing through the present, Defendants and their co-conspirators engaged in a continuing agreement, understanding, and conspiracy in restraint of trade to restrict output and to artificially raise, fix, maintain or stabilize the prices of Plasma-Derivative Protein Therapies in the United States.

217. Based on the foregoing, and on information and belief, in formulating and effectuating the contract, combination or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to restrict output and to artificially raise, fix, maintain, or stabilize the price of Plasma-Derivative Protein Therapies sold in the U.S. These activities included:

(a) Defendants participating in meetings, conversations and communications to discuss the supply and price of Plasma-Derivative Protein Therapies in the United States; and

(b) Defendants agreeing during those meetings, conversations and communications to restrict output and to charge prices at specified levels and otherwise to fix, raise, maintain or stabilize prices of Plasma-Derivative Protein Therapies sold in the United States.

218. Defendants and their co-conspirators engaged in the activities described above for the purpose of effectuating the unlawful agreements described in the Complaint.

219. Throughout the Class Period, Plaintiff and the other Class members purchased Plasma-Derivative Protein Therapies from Defendants (or their subsidiaries or controlled affiliates) or their co-conspirators at supra-competitive prices.

220. Defendants' contract, combination or conspiracy constitutes an unreasonable restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

#### **EFFECTS OF THE CONSPIRACY**

221. As a result of Defendants' unlawful conduct, Plaintiff and the other Class members have been injured in their business and property because they have paid more for Plasma-Derivative Protein Therapies than they would have paid in a competitive market.

222. The unlawful contract, combination or conspiracy has had at least the following effects:

(a) price competition in the markets for Plasma-Derivative Protein Therapies has been artificially restrained;

(b) prices for Plasma-Derivative Protein Therapies sold by Defendants have been raised, fixed, maintained, or stabilized at supra-competitive levels; and

(c) purchasers of Plasma-Derivative Protein Therapies from Defendants have been deprived of the benefit of free and open competition in the Plasma-Derivative Protein Therapies markets.

### **FRAUDULENT CONCEALMENT**

223. Plaintiff and members of the Class did not discover, and could not have discovered through the exercise of reasonable diligence, the existence of the conspiracy alleged herein until May 27, 2009, when the FTC's redacted complaint was filed.

224. Because Defendants' alleged conspiracy was kept secret until May 27, 2009, Plaintiff and members of the Class before that time were unaware of Defendants' unlawful conduct alleged herein, and they did not know before that time that they were paying supra-competitive prices for Plasma-Derivative Protein Therapies throughout the United States during the Class Period.

225. The affirmative acts of the Defendants alleged herein, including acts in furtherance of the conspiracy, were wrongfully concealed and carried out in a manner that precluded detection.

226. By its very nature, Defendants' conspiracy was inherently self-concealing. Plasma-Derivative Protein Therapies are not exempt from antitrust regulation, and thus, before May 27, 2009, Plaintiff reasonably considered the plasma-derivative protein therapy industry to be a well-regulated, competitive industry.

227. In addition, as detailed previously, Defendants, through their trade association, the PPTA, intentionally over-reported the supply of Plasma-Derivative Protein Therapies to the marketplace during the class period in order to avoid governmental and public scrutiny of their sales and marketing practices, and to conceal the existence of the shortages created by their conspiracy.

228. Under the circumstances surrounding Defendants' pricing practices, Defendants' acts of concealment were more than sufficient to preclude suspicion by a

reasonable person that Defendants' pricing was conspiratorial. Accordingly, a reasonable person under the circumstances would not have been alerted to investigate the legitimacy of Defendants' Plasma-Derivative Protein Therapies prices before May 27, 2009.

229. Plaintiff and members of the Class could not have discovered the alleged conspiracy at an earlier date by the exercise of reasonable diligence because of the deceptive practices and techniques of secrecy employed by Defendants and their co-conspirators to avoid detection of and fraudulently conceal their conspiracy.

230. Because the alleged conspiracy was both self-concealing and affirmatively concealed by Defendants and their co-conspirators, Plaintiff and members of the Class had no knowledge of the alleged conspiracy, or of any facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed, until May 27, 2009, when the FTC complaint, and its corresponding factual allegations of anti-competitive conduct concerning Plasma-Derivative Protein Therapies, was first publicly disseminated.

231. None of the facts or information available to Plaintiff and members of the Class prior to May 27, 2009, if investigated with reasonable diligence, could or would have led to the discovery of the conspiracy alleged herein prior to that date.

232. As a result of Defendants' fraudulent concealment of their conspiracy, the running of any statute of limitations has been tolled with respect to any claims that Plaintiff and members of the Class have alleged in this Complaint.

233. Defendants and their co-conspirators engaged in a successful anti-competitive conspiracy concerning Plasma-Derivative Protein Therapies, which they affirmatively concealed, at least in the following respects:

(a) By communicating secretly to discuss output and prices of Plasma-Derivative Protein Therapies in the United States;

(b) By agreeing among themselves not to discuss publicly, or otherwise reveal, the nature and substance of the acts and communications in furtherance of their illegal scheme;

(c) By mis-reporting supply to HHS in order to conceal the dangerous shortages caused by their conspiracy; and

(d) By falsely denying the existences of supply shortages for Plasma-Derivative Protein Therapies.

234. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiff's and the Class's claims have been tolled.

#### **CLASS ACTION ALLEGATIONS**

235. Plaintiff brings this action on behalf of itself and as a class action under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the following class (the "Class"):

All persons and entities in the United States who purchased Plasma-Derivative Protein Therapies directly from any Defendant at any time from at least as early as July 1, 2003 ("Class Period") through the present. Excluded from the Class are Defendants, their parent companies, subsidiaries and affiliates, any co-conspirators, federal governmental entities and instrumentalities of the federal government.

236. Plaintiff believes that there are thousands of Class members located throughout the United States, the exact number and their identities being known by Defendants, making the Class so numerous and geographically dispersed that joinder of all members is impracticable.

237. There are questions of law and fact common to the Class, including:

- (a) Whether Defendants and their co-conspirators engaged in a combination and conspiracy among themselves to restrict output and to fix, raise, maintain or stabilize the prices of Plasma-Derivative Protein Therapies sold in the United States;
- (b) The identity of the conspiracy's participants;
- (c) The duration of the conspiracy alleged in this Complaint and the acts carried out by Defendants and their co-conspirators in furtherance of the conspiracy;
- (d) Whether the alleged conspiracy violated Section 1 of the Sherman Act;
- (e) Whether the conduct of Defendants and their co-conspirators, as alleged in this Complaint, caused injury to the business and property of Plaintiff and the other Class members;
- (f) The effect of the conspiracy on the prices of Plasma-Derivative Protein Therapies sold in the United States during the Class Period; and
- (g) The appropriate Class-wide measure of damages.

238. Plaintiff's claims are typical of the claims of Class members, and Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff and all members of the Class are similarly affected by Defendants' wrongful conduct in violation of the antitrust laws in that they paid artificially inflated prices for products purchased directly from Defendants or their co-conspirators. Plaintiff's claims arise out of the same common course of conduct giving rise to the claims of the other Class members. Plaintiff's interests are coincident with, and not antagonistic to, those of the other Class members.

239. Plaintiff is represented by counsel who are competent and experienced in the prosecution of antitrust and class action litigation.

240. The prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for Defendants.

241. The questions of law and fact common to the members of the Class predominate over any questions affecting only individual members.

242. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The Class is readily definable. Prosecution as a class action will eliminate the possibility of repetitious litigation. Treatment as a class action will permit a large number of similarly situated persons to adjudicate their common claims in a single forum simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would engender. This action presents no difficulties in management that would preclude maintenance as a class action.

### **CAUSE OF ACTION**

#### **VIOLATION OF SECTION 1 OF THE SHERMAN ACT - 15 U.S.C. § 1**

243. Plaintiff incorporates and re-alleges each allegation set forth in the preceding paragraphs of this Complaint.

244. Beginning at least as early as July 1, 2003, and continuing thereafter, Defendants and their co-conspirators, by and through their officers, directors, employees, agents, or other representatives, entered into a continuing agreement, understanding, and conspiracy in restraint of trade to restrict output and to artificially raise, fix, maintain, or

stabilize prices for Plasma-Derivative Protein Therapies in the United States in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

245. Plaintiff and the other Class members have been injured in their business and property by reason of Defendants' unlawful combination, contract, conspiracy and agreement. Plaintiff and Class members have paid more for Plasma-Derivative Protein Therapies than they otherwise would have paid in the absence of Defendants' conduct. This injury is of the type the federal antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

246. Accordingly, Plaintiff and Class members seek damages, to be trebled pursuant to federal antitrust law, and costs of suit, including reasonable attorneys fees.

#### **DEMAND FOR JURY TRIAL**

247. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a jury trial as to all issues triable by a jury.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays as follows:

A. That the Court determine that this action may be maintained as a class action under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure.

B. That the contract, combination or conspiracy, and the acts done in furtherance thereof by Defendants and their co-conspirators be adjudged to have violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

C. That judgment be entered for Plaintiff and Class members against Defendants for three times the amount of damages sustained by Plaintiff and the Class as allowed by law.



D. That Plaintiff and the Class recover pre-judgment and post-judgment interest as permitted by law.

E. That Plaintiff and the Class recover their costs of the suit, including attorneys' fees, as provided by law.

F. That Defendants be enjoined from continuing their participation in the alleged conspiracy.

G. For such other and further relief as is just and proper under the circumstances.

Dated: December 18, 2009

/s/ Carol V. Gilden

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